CLAIMS

1. A computer-implemented method of validating a computer system comprising the steps of:

(i) receiving data representative of a plurality of requirements for said computer system;

(ii) generating a validation plan based on said received data;

(iii) determining a computing environment appropriate to said computer system based on said received data;

(iv) generating a plurality of tests to be performed during an implementation of said validation plan;

(v) presenting said tests to a user as part of said implementation;

(vi) receiving responses from said user as to a status of said tests;

(vii) generating a validation report based on said responses;

(viii) presenting a non-validation message if said validation report indicates said system failed one or more of said tests;

(ix) presenting a validation message if said validation report indicates said system meets said tests; and,

(x) repeating one or more of the foregoing steps until said validation report indicates said system meets said tests.

2. A computer-implemented method of validating a computer system comprising the steps of:

receiving a plurality of validation requirements for said computer system;

receiving data representative of the results of performing each validation requirement, said results including whether a particular requirement was achieved and exception reports for each requirement that was not achieved; and,

generating a report for each of said requirements, said report including a message indicating whether said system is validated if a defined set of said requirements are achieved.

3. The method according to claim 2 wherein said computer system is a computer system used in the pharmaceutical industry.

4. The method according to claim 2 wherein said computer system is a computer system used in the health care industry.

5. The method according to claim 2 wherein said validation requirements include at least one of a installation qualification, operational qualification, performance qualification, a third-party qualification.

6. The method according to claim 4 wherein said third-party qualification is based on 21 CFR Part 11.

7. The method according to claim 6 wherein said installation qualification, said operational qualification, said performance qualification, and said third-party qualification each include at least one of a hardware requirement, a user requirement, a test objective, and a test instruction.

8. The method according to claim 6 wherein said validation requirement further includes an audit respective to said installation qualification, said operational qualification, said performance qualification, and said third-party qualification.

9. The method according to claim 8 wherein said audit is comprised of predefined checklist reflecting best practices applicable to an identifiable type of said system.

10. The method according to claim 2 wherein said report indicates that said requirements are not achieved unless an affirmative response that each requirement was achieved has been received.

11. The method according to claim 2 comprising the additional step of presenting a report summarizing each of said requirements.

12. An apparatus for validating a computer system comprising:

an input means for receiving a plurality of validation requirements for said computer system;

said input means additionally for receiving data representative of the results of performing each validation requirement, said results including whether a particular requirement was achieved and exception reports for each requirement that was not achieved; and,

a processing means for generating a report for each of said requirements, said report including a message indicating whether said system is validated if a defined set of said requirements are achieved.

13. The apparatus according to claim 12 wherein said computer system is a computer system used in the pharmaceutical industry.

14. The apparatus according to claim 12 wherein said computer system is a computer system used in the health care industry.

15. The apparatus according to claim 12 wherein said validation requirements include at least one of a installation qualification, operational qualification, performance qualification, a third-party qualification.

16. The apparatus according to claim 15 wherein said third-party qualification is based on 21 CFR Part 11.

17. The apparatus according to claim 16 wherein said installation qualification, said operational qualification, said performance qualification, and said third-party qualification each include at least one of a hardware requirement, a user requirement, a test objective, and a test instruction.

18. The apparatus according to claim 16 wherein said validation requirement further includes an audit respective to said installation qualification, said operational qualification, said performance qualification, and said third-party qualification.

19. The apparatus according to claim 18 wherein said audit is comprised of predefined checklist reflecting best practices applicable to an identifiable type of said system.

20. The apparatus according to claim 12 wherein said report indicates that said requirements are not achieved unless an affirmative response that each requirement was achieved has been received.

21. The apparatus according to claim 12 comprising additional means for presenting a report summarizing each of said requirements.

22. A readable media storing a set of instructions executable on a computing device to perform the following steps:

receiving a plurality of validation requirements for said computer system;

receiving data representative of the results of performing each validation requirement, said results including whether a particular requirement was achieved and exception reports for each requirement that was not achieved; and,

generating a report for each of said requirements, said report including a message indicating whether said system is validated if a defined set of said requirements are achieved.

23. A method of restricting access to a computing apparatus comprising the steps of:

delivering a computer-based training session to a user, said session for instructing said how to operate said apparatus;

generating a unique user code respective to said user provided said user successfully completes said training session;

presenting a user-login dialogue on said apparatus, said dialogue requesting an identification of said user and said user code;

allowing access to said computing apparatus if a received identification and a received user code match said user and said user code and otherwise refusing access to said computing apparatus.